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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,050	06/20/2001	Liat Mintz	2786-0177P	2695

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/884,050

Examiner

Dong Jiang

Applicant(s)

MINTZ ET AL.

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-- Th MAILING DATE of this c mmunication appears on th cover sh et with the correspondence addr ss --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☒ This action is FINAL.
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) 6-13, 17 and 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 18, 19, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 and 17-32 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12 & 13.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED OFFICE ACTION**

Applicant's amendment in paper No. 14, filed on 30 May 2003 is acknowledged and entered. Following the amendment, claims 14-16 are canceled, claims 1 and 18 are amended, and the new claims 31 and 32 are added.

Currently, claims 1-13 and 17-32 are pending, and claims 1-5, 18, 19, 31 and 32 are under consideration.

#### **Withdrawal of Objections and Rejections:**

All objections and rejections of claims 14-16 are moot as the applicant has canceled the claim.

The rejection of claims 1-5, 18 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The rejection of claims 1-5, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Keck et al., US 5,240,848, is withdrawn in view of applicant's amendment and argument.

#### **Formal Matters:**

Claims 2 and 3 are objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend from claim 1, which is drawn to an isolated nucleotide sequence of SEQ ID NO:1 (part (a)), and is not further limited by claims 2 and 3, which are drawn to % variants of SEQ ID NO:1, and have broader scopes.

#### **Objections and Rejections under 35 U.S.C. 112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 2 and 3 remain rejected, and claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a nucleic acid of SEQ ID NO:1, and a nucleic acid encoding a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for claims to % variants of SEQ ID NO:1 (claims 2, 3 and 31), for the reasons set forth in the last Office Action, paper No. 11, mailed on 02 January 2003, at page 4.

Applicants point out that the Examiner overlooked the alternative embodiment (d) in claim 1 (now present in the new claim 31) when making this rejection in the last Office Action. The Examiner would like to thank applicants for pointing out this matter, and notices that applicants have responded correctly and accordingly as the rejection were made to include claim 1.

Applicants argument, filed on 30 May 2003 (paper No. 14) has been fully considered, but is not deemed persuasive for reasons below.

At page 6 of the response, the applicant argues that new claim 31, reciting a 70% level of homology, includes a limitation of two biological activities associated with VEGF, and that this amendment addresses the Examiner's basis for the instant rejection. This argument is not persuasive because, while the new claim 31 recites functional limitation, the issue remains for claims 2 and 3, as the independent claim 1 does not recite any functional limitation. The specification merely discloses *one* nucleic acid sequence, SEQ ID NO:1, and no % variants thereof meeting the limitations of the claims were ever identified or particularly described. Additionally, as no functional limitation associated with the variants in the claims, the skilled artisan would not know how to use a nucleic acid encoding an inactive polypeptide variant of SEQ ID NO:2. Therefore, it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to use the inactive variants for any purpose stated in the specification.

With respect to claim 31, although the claim recites functional limitation, a 30% sequence variation at nucleotide level may result in about 90% change at the level of amino acid sequence. It would not be reasonable to predict that a polypeptide variant having 10% sequence homology to SEQ ID NO:2 would retain the desired functional activity. The specification

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provides neither clear direction or enough guidance, nor working example to teach how to make a commensurate number of the claimed species. As such, it would require undue experimentation to practice the invention in a manner commensurate in scope with the claim. This issue would also apply to claim 2 if applicants amend the claim to recite the functional limitation.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-5, 18, 19, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Schreiner et al., US 6,352,975 B1.

Schreiner discloses a nucleic acid molecule, SEQ ID NO:6, which is 444 nucleotides in length, comprises nucleotides 1-424 of SEQ ID NO:1 (426 nucleotides total) of the instant case with 99.8% sequence similarity (see computer printout of the search results). Schreiner's nucleic acid SEQ ID NO:6 encodes a polypeptide of a human VEGF splice variant, SEQ ID NO:1 (147 amino acid residues), which mature form is 121 amino acids in length (VEGF<sub>121</sub>), and comprises amino acid sequence of SEQ ID NO:2 (141 amino acid residues) of the instant case with 100% sequence identity (see computer printout of the search results). The mature form of the instant SEQ ID NO:2 is 114 amino acids in length. The referenced sequence, therefore, anticipates claims 1-3 and 31 as being a nucleic acid *consisting essentially of* a polynucleotide having a nucleotide sequence of SEQ ID NO:1, or having a nucleotide sequence encoding the amino acid of SEQ ID NO:2. With respect to the functional limitation in claim 31, as the prior art sequence meets the sequence limitation of the claim, the functional property is inherent for the same molecule. Further, Schreiner teaches that the practice of the present invention will employ *conventional* techniques of molecular biology (including *recombinant* techniques), ..., which are within the skill of the art, and cites multiple sources of the literature accordingly

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(column 7, lines 22-39). As Schreiner's polypeptide is produced recombinantly, which necessarily involves an expression vector comprising said nucleic acid, and a host cell thereof, the reference, therefore, also anticipates claims 4, 5, 18, 19, and 32.

**Conclusion:**

No claim is allowed.

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**Advisory Information:**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, reading "Lorraine Spector". The signature is fluid and cursive, with a large loop at the end of the last name.

**LORRAINE SPECTOR  
PRIMARY EXAMINER**

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
7/18/03